American Academy of Orthopaedic Surgeons®

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June 10, 1999

99N-0035

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Jane E. Henney, MD
Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Henney:

The American Academy of Orthopaedic Surgeons (AAOS), representing over 16,000 Board certified orthopaedic surgeons, is pleased to take this opportunity to express our support for the reclassification of four preamendment Class III orthopaedic medical devices. These devices were listed in the proposed rule in the Federal Register that appeared on Monday, March 15, 1999. (Docket No. 99N-0035).

Our comments are limited only to the reclassification of these four orthopaedic devices listed in the proposed rule. They are:

- Elbow joint metal/polymer constrained cemented prosthesis (21 CFR 888.3150);
- Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (21 CFR 888.3540);
- Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650); and
- Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660).

We share the concerns of the FDA in ensuring that safe and effective products enter the marketplace. We remain committed to protecting consumers and our patients, while at the same time making sure that the latest technologies in safe orthopaedic devices come to the marketplace through streamlined regulatory review.

The orthopaedic clinical and research community has worked closely with the Orthopaedic Surgical Manufacturers Association (OSMA) to develop the petitions in support of the reclassification of these four orthopaedic devices, which were formally submitted to the FDA in 1997. Many Academy Fellows provided balanced expertise and clinical experience to assemble the supporting data for these reclassification petitions. We believe that these data represent the best clinical evidence to date to support the reclassification of these devices from Class III to Class II.

With regard to the reclassification of total shoulder and total elbow prostheses, in the late 1970s, the FDA Orthopaedic and Rehabilitation Devices Panel recommended their reclassification from Class III to Class II. At the time, the FDA disagreed, and believed that there were insufficient data to warrant any action. In the two decades that have elapsed, the AAOS believes that appropriate peer reviewed clinical data now exist to support the reclassification, as included in the reclassification petitions submitted by OSMA. Specifically, documented clinical experience and peer reviewed published clinical results provide reasonable assurances of the safety and effectiveness of the devices, as well as establish the risks associated with the device that are controllable through adherence to standards, appropriate preclinical testing, labeling, and good surgical technique.

It is appropriate that elbow joint metal/polymer constrained cemented prostheses and shoulder joint metal/polymer non-constrained and semi-constrained cemented prostheses now be reclassified as Class II devices.

With regard to the reclassification of patellofemoral joint prostheses (PFJ), the AAOS believes that long-term data also exist that address the risk, which originally resulted in the placement of these devices into Class III. As the FDA is aware, there is a relatively limited population and indications for which PFJ may be used, as compared to total knee arthroplasty. Nevertheless, published peer reviewed literature clearly demonstrate reasonable assurance of the safety and effectiveness of PFJ, as well as the controllable risks. Also, there is considerable experience with femoral and patellar components of total knee systems with which PFJ devices have some similarities. Finally, because the patient population for this procedure is a small one, the AAOS believes that unless PFJ is reclassified as a Class II device, there would be no other reasonable regulatory path by which PFJ could come to market and be made available to our patients.

We commend FDA in its decision to reclassify these orthopaedic devices, and we look forward to continuing to work with you in the future in the reclassification of other orthopaedic devices for which we believe clinical data support their redesignation as Class II devices.

Thank you for your actions in this matter.

Sincerely,

William W. Tipton, Jr., MD
Executive Vice President

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